DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

3175681

SEP 19 2001

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. William H. McGrail
Vice-President, Research & Development
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: Candela Mid IR Diode Laser System
(a.k.a. Smoothbeam), K002421

Dear Mr. McGrail:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed additional promotional materials for the Candela Mid IR Diode Laser (a.k.a. Smoothbeam). This product is manufactured by Candela Corporation and is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Smoothbeam was cleared under section 510(k) of the Act and is intended for use in dermatology for incision, excision, ablation, and vaporization with hemostasis of soft tissue. Additionally, the Candela Dynamic Cooling device was cleared to cool the skin prior to laser treatment and for reducing pain during laser treatment.

In a previous letter from our office dated June 27, 2001, we advised you that promotional claims appearing on your web site or in other promotional materials, implying that Smoothbeam may be used for cosmetic purposes, for skin renewal and/or rejuvenation, or for stimulating collagen remodeling or deposition, were not cleared by the agency as part of your 510(k) submission. Your response of July 6, 2001 made a commitment to revise your web site and promotional materials by September 6, 2001 to remove such claims.

We have re-reviewed your web sites at the Internet address: http://www.smoothbeam.com and http://www.clzr.com, as well as a recent 2001 advertisement titled, Discover Smoothbeam. And send your patients back in time, and an April 3, 2001 press release titled, Candela Begins Worldwide Shipment of Smoothbeam: A Revolutionary Diode Laser for Skin Renewal. As of September 17, 2001, these materials continue to make claims for the Smoothbeam stating that

the device may be used for cosmetic purposes, for the treatment of skin renewal and/or rejuvenation, and for initiating collagen remodeling and deposition. Representative examples of such statements include, but are not limited to the following:

From the advertisement:

-"Skin renewal was never so easy and affordable"

-"It's about time someone came up with a way to fight the effects of aging. The Smoothbeam Laser is a whole new way to approach skin renewal"

-"Featuring our patented LASR (laser-assisted skin renewal) process...Smoothbeam targets and heats collagen in the upper dermis while protecting the epidermis, stimulating new collagen formation"

From the web:

-"Because the wavelength of the Smoothbeam is gently absorbed by the upper layer of the dermis, what we're seeing over time is gradual improvement in the quality, tone, texture, and feel of the skin" (By David J. Goldberg, M.D., Skin Laser and Surgery Specialist of New York)

-"Discover Smoothbeam. The new non-invasive way to renew skin"

-"The subsequent healing process leads to new collagen deposition"

-Smoothbeam is an elegant, fairly painless method for improving skin without anybody knowing that anything has been done"

-"The patented LASR process. Advanced technology for collagen remodeling"

From Candela's quarterly newsletter titled, Wavelength (Spring, 2001), Part No. 0920-20-0012 Rev.01:

-"New non-ablative skin renewal laser technology demonstrated at meetings in Europe, Asia, & US"

-"Candela warmed up the winter of 2001 with announcements and demonstrations of the exciting new Smoothbeam skin renewal laser at physicians and key persons meetings in Paris, Tokyo, and Bangkok in January, and in Washington, D.C. in March" (emphasis added)

-"The Smoothbeam takes skin renewal to new levels..."

From the April 3, 2001 press release:

-"Candela is pleased to report the first shipments of Smoothbeam, its newly introduced diode-based skin renewal laser"

-"Clinically we see it (sun-damaged or aging skin) that has lost its tone and texture. The unique 1450 nm wavelength of the Smoothbeam is absorbed by water in the damaged collagen. ...This leads the body to

create new collagen that has better direction – it's thicker, and it leads to better tone and quality of the skin"

Candela also references the body's natural healing response and its association with collagen remodeling in pictorial representations at http://www.smoothbeam.com/LASR_page.htm.

Continued promotion of the Candela Smoothbeam Laser for claims implying that Smoothbeam may be used for cosmetic purposes, for the treatment of skin renewal and/or rejuvenation, for initiating collagen remodeling and deposition, or for fighting the effects of aging cause the Smoothbeam to be misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii) and section 510(k) of the Act, and the device was not found to be substantially equivalent to a predicate device.

The Smoothbeam is also adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

Finally, we note that your web site contains a list of upcoming cosmetic laser workshops scheduled from now through January, 2002 which purport to provide live patient demonstrations and hands-on laser experience using the Smoothbeam laser. Candela should ensure that your presentations, demonstrations, and any lectures at these workshops are strictly limited to the cleared intended use of your device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Smoothbeam device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New England District Office (HFR-NWE200), One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Sincerely yours,

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

Gerard E. Puorro
President and Chief Executive Officer